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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/018,160 | 11/01/2001 | Ronald Alan Coffee | 13401 | 2938 |

24116 7590 06/06/2005

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| EXAMINER |
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OH, SIMON J

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| ART UNIT | PAPER NUMBER |
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1618

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|--|--|--|
| <p align="center">Office Action Summary</p> | <p>Application No.</p> <p align="center">10/018,160</p> | <p>Applicant(s)</p> <p align="center">COFFEE ET AL.</p> | |
| | <p>Examiner</p> <p align="center">Simon J. Oh</p> | <p>Art Unit</p> <p align="center">1618</p> | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-9,11,13-16,18-26,28-32,34-48,51,52 and 55-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-26,28,43,47 and 48 is/are allowed.
- 6) ☒ Claim(s) 4-9,11,13-16,29-32,34-42,44-46,51,52 and 55-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's petition for extension of time, amendment, and response, all received on 24 February 2005.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 49, 50, 53, and 54 under 35 U.S.C. 103(a) as being unpatentable over Coffee in view of Sturzenegger *et al.* and Roche *et al.* is rendered moot with the cancellation of those claims.

The rejection of Claims 18-26, 28, 43, 47, and 48 under 35 U.S.C. 103(a) as being unpatentable over Coffee in view of Sturzenegger *et al.* and Roche *et al.* is hereby withdrawn.

The rejection of Claims 4-9, 11, 13-16, 29-32, 34-42, 44-46, 51, 52, and 55-60 under 35 U.S.C. 103(a) as being unpatentable over Coffee in view of Sturzenegger *et al.* and Roche *et al.* is hereby withdrawn.

Claims 4-9, 11, 13-16, 29-32, 34-42, 44-46, 51, 52, and 55-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee.

The Coffee document discloses processes and apparatuses for forming material by electrohydrodynamic comminution (See Abstract; and Page 4, Lines 1-4). In one aspect, the

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processes and apparatuses disclosed within the document is capable of producing various solid and partially solid forms, such as fibers, fiber segments, fibrils, droplets, particles, webs, and mats. This formed matter may also contain a biologically active ingredient (See Page 2, Line 12 to Page 3, Line 15). Fibers, fiber fragments, and particles of biological material, such as fibrin or collagen may also be formed using the processes and apparatuses (See Page 6, Lines 13-18). Alternatively, the active ingredient may be provided as a coating or core of the fibers, fibrils, or particles (See Page 5, Lines 7-28). Active ingredients may be supplied onto fibers, fibrils, or droplets in the form of a liquid that is dispensed through an outlet nozzle (See Page 22, Lines 23-33). The reference discloses that fibers have been successfully spun with polyhydroxybutyric acid, a resorbable polymer, and with polyvinyl alcohol, a water-soluble polymer (See Page 19, Lines 20-23). In the formation of material provided by the methods and apparatuses disclosed in the reference, the supply of the material may be assisted by an air or inert gas flow (See Claim 32; and Page 30, Lines 27-31). When a melt is used as the material to be formed by the apparatuses and processes disclosed in the reference, the temperature of this material may be controlled by quenching using a cold air or inert gas stream (See Page 11, Lines 17-22).

The Roche *et al.* patent is used here merely as a teaching reference to show that additives such as saccharin and peppermint flavoring are commonly known in the pharmaceutical arts (See Column 8, Lines 31-58).

As explained above, the Roche *et al.* patent is relied upon merely as a teaching reference. It is the position of the examiner that one of ordinary skill in the art could combine the collective disclosures of the prior art with a reasonable expectation of success. Though the prior art is silent with respect to a cutting step in the disclosed method of production, as the prior art has

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disclosed the manufacture of particles in addition to fibers and mats, it is the view of the examiner that the use of a cutting step is would be within the level of skill of one of ordinary skill in the art. It is also the position of the examiner that the selection of fish gelatin over gelatin of other sources is not a patentable distinction, as the selection of a particular type of gelatin is considered to be well within the purview of one of ordinary skill in the art, absent a showing of unexpected results by the applicant. Claim limitations containing specific amounts of specific ingredients are considered by the examiner to be attainable by one of ordinary skill in the art through routine experimentation, and as such as not considered to impart a patentable distinction above the prior art, without a showing of unexpected results. Claim limitations reciting specific moist tissue surfaces are considered by the examiner to be recitations of intended use, and thus do not carry patentable weight.

Thus, the instantly claimed invention is prima facie obvious.

Response to Arguments

Applicant's arguments with respect to Claims 4-9, 11, 13-16, 29-32, 34-42, 44-46, 51, 52, and 55-60 have been considered but are moot in view of the new grounds of rejection.

Allowable Subject Matter

Claims 18-26, 28, 43, 47, and 48 are allowed.

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Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1618

sj0


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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